

PATENT

I THE UNITED STATES PATENT AND TRADEMARK OFFICE

ROBINSON et al.

CASE NO: AM100401

SERIAL NO: 10/705,716

GROUP ART UNIT: 1653

FILED: NOVEMBER 10, 2003

EXAMINER: A. DESAL

FOR: A NOVEL PTH RESPONSIVE GENE

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

In the Non-Final Office Action mailed on June 15, 2006, the Examiner rejected claims 8-12 and 38-42 under 35 U.S.C. § 102(a) as being anticipated by Tanner SM et al. (Proc. Natl. Acad. Sci. USA 98:13901-06 (2001)). Specifically, the Examiner asserted that SEQ ID NO:2 and SEQ ID NO:10 of the above-identified application were anticipated by Tanner SM et al.'s deposit of polynucleotide sequences that encode the polypeptides of SEQ ID NO:2 and SEQ ID NO:10. Reference to SEQ ID NO:10 has been deleted from the present application.

I, John Robinson, declare that the amino acid sequence at issue, SEQ ID NO:2, was reduced to practice in the United States prior to the online publication date of Tanner SM *et al.* I note that my declaration is to be construed as swearing behind the online publication date of the Tanner SM *et al.* reference, which the website for PNAS states is November 13, 2001 (see http://www.pnas.org/content/vol98/issue24/). Further to this declaration, I attach signed notebook pages (Exhibit 1), with dates reducted, that exemplify the reduced to practice sequence (see highlighted text).

As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I

Date

Ser. No. 10/705,716 Docket No. AM100401

also declare that all statements were made with knowledge that willful false statements, and the like, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and any such willful false statements may jeopardize the validity of either the patent application or any patent issuing thereon.

Respectfully Submitted,

John A. Robinson

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Exhibit 2

From:

Richard Sheldon [RSheldon.2BURTT_A.AND_N@gvn002m.gv.us.pri.wyeth.com]

Sent:

To:

REDACTED
GSturrock.GICE01.USCE01@gvn002m.gv.us.pri.wyeth.com

Subject:

Sequencing Request 2368 Final Results





ID72_hum ID72_DF04 Reference.Tonsensus_92

Gunilla,

Here is the completed sequence for clone DF04Qp1 for ID72. There are a few differences with the provided reference sequence:

- 1. 1465 C to T shift
- 2030 deletion of C
- 2453 deletion of C

I will attach the reference sequence and consensus sequence in FASTA format. The clone is stored in the second -80 freezer on the right side of the lowest shelf., The DNA is in my small refrigerator in a box labeled "Gunilla's Projects."

rick

Exhibit 2 (continued)

ID72_human_Reference.TXT

>ID72_human_Reference ATGGGCTGCGGCGGAGCCGGGCGGATGCCATCGAGCCCCGCTACTACGA GAGCTGGACCCGGGAGACAGAATCCACCTGGCTCACCTACACCGACTCGG CTGCACTCGGGCATGCTGGAAGATGGACTGCCCTCCAATGGTGTGCCCCG ATCTACAGCCCCAGGTGGAATACCCAACCCAGAGAAGAAGACGAACTGTG AGACCCAGTGCCCAAATCCCCAGAGCCTCAGCTCAGGCCCTCTGACCCAG AAACAGAATGGCCTTCAGACCACAGAGGCTAAAAGAGATGCTAAGAGAAT GCCTGCAAAAGAAGTCACCATTAATGTAACAGATAGCATCCAACAGATGG ACAGAAGTCGAAGAATCACAAAGAACTGTGTCAACTAGCAGAGAGTCCAA GCAGAAGGCAGATGGACTTCTTCAGTGTCCTTCACGGCACTGGATCCCA TCAAAGAACCTTGAAGAAGTGGCTGCCCCTTGCTGGACCTGAATTCTACT GAGTCCCTGGCAAGACTGTCTTACCTGGCAGCAAACTGCTGCCTGATTTG TTGGGACCTTCTGAGCCTTCTACTTATCATGTAAATGTATTGGCACAGTG AACTCCTGTAATACGGTCTGGTGTAAAAGTAGTGAGTTAAAGCTACAGGT CAGTTTATGAAACAGAAAAGTAGGAATGCATTTTCTGGGTGAAAGAGTCA CACCTTAGTGCTATAACTCTCCTGCCCATGATAGTGTATTCTGTTTCAGG CAAGCTTATTCTTTCCTTTTCATTTTAAATATTGTCATTACAAATCTT ACCAGGTTCACTTAAAAGCTGGCTTTCATCCAACTCTAAACCCACATATT GAAAAAATCAAGGTACAGGAAAACTCCTTGTTATCCTTGTTTCCTTAGCT TGGTATGAGACAGATCGGATCCAGTTTCCCATGCACCAACCCACTGCCCA TGGCATGTCTTTGGGAGGTGTCTGTGAAGCAGTCATACCTGCTCCTCATC TGCCTGGAAAGTCCTCCTATTCCAGTGTCCATGTTGGCCTCCAGTCCTTA ATGTCACCATGCTTGTGGCCAATGCATCCAAATAAGGATACCCCTCAGGG CTCAGCTAGACATTTTGCATAGCTTTCCAGTTCCCTTTGCTTGT CTTCTTGACTGTCTTCCCTCTCTATCGGGGTCACTTGCAATTGTTAATCA AAGATTGAACACTGCGTAGGAGAGGGGAGATGATCCAGAGACATGTGGCAG CAGGCATGGCTTCCCCTTGGCCTCTGTACACTGCCCCAGGACTGTCAT TTTGGCATCTGCAAAGGAATCACTTTAGAAAGCCAGCACCTGGTTGATGT **GTATTCATACTGACATTAGATTGATGTGCACTGCATTAGAAATGAGGTAG** CTGACACAGAAAAAGGATGTTTTGATAGGAATAATTTTCTAGTATGTCTT GAAACATGTTCATCTGGAAGTATTTTCCTCCAAAGTAATGTAGCATGATT TTTCAAGGATTGTTAACATGCCTGGGATTGGGAAAGATAGGACTAAAGTT GTGCCAAACTATATCAATAAATTCCATGTTTAGCAGAAATAGGCAGCCTA TTGGTGTTATGTTATGTAACATAGTCCAGAGAACTGACATGCAGGTCAA AAGTCAGATACGCAACCTCCTTATCTGCTAACTCTGTTATTCTTCAAACA CAAGTGGGTAGTGTCATTTTTCCTTCCCTTCCTTCCATTGGCAGATTGTA TATTTATTCACAAAACATTAAATGTCCATCCTGTGCCAGGTACTATGCAG AACAGTGACTTCATAACTAGGAGACTGAATTAGACCCTTAAGGTATAGTG TGTGTTGCAAATCACTCTGCAATGGAAACTTTTATATTCAGGGTAGGTTT GTGTCTTAAACTAGGTGTTCTAATCAATGTACAAGACTTTACCATACACG CAACTTTAGTTTTTCTAAACCTTCATCATTTTGTGATTCTTTGAGAAAGG GCTTTTAGGAACTTTATGTTCTAAAAAATGTTTTTAACAATAATAAGATA AAAGAAAAACCTGTGATTCATATGTCCCCACTGGCATTACTCAGCAGGAG CCCCCAGCTGCCAAAGGTTGGCAGTGATCCTGCAAGTTCAAGGGCTCTT TCTCCCTGGGGATGTGCTTTGTGGCTTCTCTTTACAGCTTTGTTTCTGCA TCAGTTCACTGCTGCATGTTTGTTTGGAATTTATCACCTTAAGAAAGTGTC TCTGTTTTATATAGAAACACTTTCTCACTTACAGGGGAGAAGGAAATGCA GGGCACATGATCTGGCCCTCCCCAGAACAATCTGGATTTCACGGAGACAG CAACCAGAAGTTAAACCATGTGACTAAAAATGCATCTGGCTACTTTTTCA TGTATGTATGAGACAGAAACTAATCCTTACTATCCTATTAGGATACCACT TTTCATTGCAAAGTTTGTGTCAATAAAGTCATTAATTTTAAACAT

Exhibit 2 (continued)

ID72_DF04QP1_Consensus_92701.tx.TXT

>ID72_DF04QP1_Consensus_92701.tx GGTACCGGTCCGGAATTCCCGGGATGCCCGGACTAGGGGCGGCGGCACC GCCGCCGCCTCCTTGCGGGCCGGGGCTGCGCCTCCGGGGCTGAGCCG CCGCCAGAGCCGACAGCCGAGCAGCCGCTGGGCGCTCCCGCGGCGCAGGA GGATGGGCTGCGGGGGGGGCGGATGCCATCGAGCCCCGCTACTAC GAGAGCTGGACCCGGGAGACAGAATCCACCTGGCTCACCTACACCGACTC GGACGCGCCCAGCGCCGCCCCGGACAGCGGCCCCGAAGCGGGCG GCCTGCACTCGGGCATGCTGGAAGATGGACTGCCCTCCAATGGTGTGCCC CGATCTACAGCCCCAGGTGGAATACCCAACCCAGAGAAGAAGACGAACTG TGAGACCCAGTGCCCAAATCCCCAGAGCCTCAGCTCAGGCCCTCTGACCC AGAAACAGAATGGCCTTCAGACCACAGAGGCTAAAAGAGATGCTAAGAGA ATGCCTGCAAAAGAAGTCACCATTAATGTAACAGATAGCATCCAACAGAT GGACAGAAGTCGAAGAATCACAAAGAACTGTGTCAACTAGCAGAGAGTCC AAGCAGAAGGGCAGATGGACTTCTTCAGTGTCCTTCACGGCACTGGATCC CATCAAAGAACCTTGAAGAAGTGGCTGCCCCTTGCTGGACCTGAATTCTA CTGAGTCCCTGGCAAGACTGTCTTACCTGGCAGCAAACTGCTGCCTGATT TGTTGGGACCTTCTGAGCCTTCTACTTATCATGTAAATGTATTGGCACAG TGCTTACATATGTTAATAAACTGCAAATGTGCAGTTCAGTTTGTCTCTTT GCAACTCCTGTAATACGGTCTGGTGTAAAAGTAGTGAGTTAAAGCTACAG GTCAGTTTATGAAACAGAAAAGTAGGAATGCATTTTCTGGGTGAAAGAGT CACACCTTAGTGCTATAACTCTCCTGCCCATGATAGTGTATTCTGTTTCA GGCAAGCTTATTCTTTCCTTCTTTCATTTTAAATATTGTCATTACAAATC TTACCAGGTTCACTTAAAAGCTGGCTTTCATCCAACTCTAAACCCACATA TTGAAAAAATCAAGGTACAGGAAAACTCCTTGTTATCCTTGTTTCCTTAG CTTGGTATGAGACAGATCGGATCCAGTTTCCCATGCACCAACCCACTGCC CATGGCATGTCTTTGGGAGGTGTCTGTGAAGCAGTCATACCTGCTCCTCA TCTGCCTGGAAAGTCCTCCTATTCCAGTGTCCATGTTGGCCTCCAGTCCT TAATGTCACCATGCTTGTGGCCAATGCATCCAAATAAGGATACCCCTCAG GGCTCAGCTAGACATTGCAATTTTGCATAGCTTTCCAGTTCCCTTTGCTT GTCTTCTTGACTGTTTTCCCTCTCTATCGGGGTCACTTGCAATTGTTAAT CAAAGATTGAACACTGCGTAGGAGAGGGGGGGGAGATGATCCAGAGACATGTGGC AGCAGGCATGGCTTCCCCTTGGCCTCTCTGTACACTGCCCCAGGACTGTC ATTTTGGCATCTGCAAAGGAATCACTTTAGAAAGCCAGCACCTGGTTGAT GTGTATTCATACTGACATTAGATTGATGTGCACTGCATTAGAAATGAGGT AGCTGACACAGAAAAAGGATGTTTTGATAGGAATAATTTTCTAGTATGTC TTGAAACATGTTCATCTGGAAGTATTTTCCTCCAAAGTAATGTAGCATGA TTTTTCAAGGATTGTTAACATGCCTGGGATTGGGAAAGATAGGACTAAAG TTGTGCCAAACTATATCAATAAATTCCATGTTTAGCAGAAATAGGCAGCC TATTGGTGTTATGTTATGTAACATAGTCCAGAGAACTGACATGCAGGTC AAAAGTCAGATACGCAACCTCCTTATCTGCTAACTCTGTTATTCTTCAAA CACAAGTGGGTAGTGTCATTTTTCCTTCCTTCCTTCCATTGGCAGATTGT ATATTTATTCACAAAACATTAAATGTCCATCCTGTGCCAGGTACTATGCA TAACAGTGACTTCATAACTAGGAGACTGAATTAGACCCTTAAGGTATAGT GTGTGTTGCAAATCACTCTGCAATGGAAACTTTTATATTCAGGGTAGGTT TGTGTCTTAAACTAGGTGTTCTAATCAATGTACAAGACTTTACCATACAC GCAACTTTAGTTTTTCTAAACCTTCATCATTTTGTGATTCTTTGAGAAAG GGCTTTTAGGAACTTTATGTTCTAAAAAATGTTTTTAACAATAATAAGAT AAAAGAAAACCTGTGATTCATATGTCCCCACTGGCATTACTCAGCAGGA GCCCCCAGCTGCCAAAGGTTGGCAGTGATCCTGCAAGTTCAAGGGCTCTT TCTCCCTGGGGATGTGCTTTGTGGCTTCTCTTTACAGCTTTGTTTCTGCA TCAGTTCACTGCTGCATGTTGTTTGGAATTTATCACCTTAAGAAAGTGTC TCTGTTTTATATAGAAACACTTTCTCACTTACAGGGGAGAAGGAAATGCA GGGCACATGATCTGGCCCTCCCCAGAACAATCTGGATTTCACGGAGACAG CAACCAGAAGTTAAACCATGTGACTAAAAATGCATCTGGCTACTTTTTCA TGTATGTATGAGACAGAAACTAATCCTTACTATCCTATTAGGATACCACT TTTCATTGCAAAGTTTGTGTCAATAAAGTCATTAATTTTAAACATAAAAA AAAAAAAAAAAAAAAAAAGGGCCGCCCCCCAGAGTATCCCTCGAG GGGCCCAAGCTTACGCGT

Exhibit 2 (continued)

Safran, Jeffrey B.

From:

Fariba Shoarinejad [SHOARIF@wyeth.com]

Sent:

Wednesday, REDACTED 11:11 AM

To:

Safran, Jeffrey B.

Subject: Fwd: Re: Your clone

And more...

>>> John A. Robinson Repair 2:57:11 PM >>>

FYI, this is when I said we would accept the human clone from Invitrogen.

John

>>> Gunilla Sturrock (EDACED 9:32:16 AM >>>

Thanks John,

I'll let Invitrogen know that we accept the clones.

Gunilla

>>> John A. Robinson (7:42 AM >>>

Hello Gunilla, the human Fragment 22 clone looks good, there is 136 bp more 5' UTR and more 3' UTR and the largest ORF from the human sequence information that you provided us is the same as the rat sequence. However, interestingly, of the 136 bp's additional 5' UTR, the first 25 bp's is odd. In a Celera search of the "assembled human sequence" we were not able to identify this first 25 bp's. However, if we search Celera's "unplaced fragments" we identified that 25 bp but it was located in a different chromosome region relative to the rest of the clone, so we are not sure what that first 25bp's is. I can tell you that we looked over 120,000 bp's 5' of the first exon that we have in the assembled human Celera sequence and we don't see that 25 bp sequence and I can tell you there is very little unsequence gaps in that 120,000bp. However, if you go further than 120,000bp's then there are more gaps and so it would be unreliable to look any further. Obviously we were trying to look for another exon 5' of our 1st exon. We looked this far because we know that intron 1 is big, 60kb. So in summary we are not sure what that first 25 bp's is. A Japanese group has recently published in the database the same sequence that we have with the same ORF that we predicted however they do not have the 25 bp of the 5' UTR that Invitrogen's clone has. We will try to do some RT-PCR with that sequence and 5' RACE to see if we have another exon. I have sent the predicted ORF amino acid sequence to Nancy to begin antibody production, but as yet we are not entirely sure whether there is another exon. John

>>> Gunilla Sturrock (CONTRO) 10:33 AM >>> Hi John,

I was wondering if you could give me an update on the Genoscope clone? Is it what you wanted? Did you get the ORF issues resolved?

Thanks,

Gunilla

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